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August 17, 2007

Commissioner for Patents
Mail Stop Appeal Brief - Patents
U. S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: **APPEAL BRIEF Response to Final Rejection Dated January 17, 2007**
U.S. Patent Application S.N. 10/071,490
Confirmation No. 2740; Filed February 7, 2002
Entitled COMPOSITIONS AND METHODS FOR FORMING AND STRENGTHENING BONE

Dear Sir:

Regarding the above-referenced Appeal Brief, the Applicant respectfully points out that throughout the prosecution of this case, although all questions were addressed and all requested changes were made, according to the suggestions specified by the Office, the present Patent Application was nevertheless rejected.

Applicants respectfully note that a Notice of Allowance was originally entered in this Application on May 24, 2006, after amendments were made pursuant to an Examiner's interview, and still the Application was not allowed.

Having followed all suggestions and requirements made by the Office, the Applicant would appreciate a favorable decision for this case, which is now under Appeal.

Yours truly,
SONNENSCHEIN NATH & ROSENTHAL

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:

J. Alexander Marchosky

Application No. 10/071,490

Confirmation No. 2740

Filed: February 7, 2002

For: COMPOSITIONS AND METHODS FOR FORMING AND STRENGTHENING BONE

Group Art Unit: 1618

Examiner: Blessing M. Fubara

I hereby certify that this document is being deposited with the United States Postal Service via EFS - WEB filing with the U.S. Patent and Trademark Office on August 17, 2007.

Sandra K. Gress

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPELLANT'S APPEAL BRIEF

Enclosed in triplicate is Appellant's Appeal Brief for the above-referenced United States Patent Application. Appellant believes that the Brief is in full compliance with 37 C.F.R. §1.192(c). Enclosed is the fee of $500.00 for the filing of this Brief.

This brief is hereby submitted within six months of the date of the Notice of Appeal was received in the United States Patent and Trademark Office. Applicant hereby petitions for a one month extension of time. A check in the amount of $120.00 is attached to cover the extension fee. It is not believed that any additional extensions of time or additional fees are required, however, Applicant hereby petitions for any such extensions of time found to be required and the Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to Account No. 19-3140. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated: August 17, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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APPEAL BRIEF

Appellant appeals from the final rejection dated January 17, 2007 of claims 97, 98, and 103-110 of the above captioned application.

The fees required under § 1.17(r), and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

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I. REAL PARTY IN INTEREST

The assignee of record, ISTO Technologies, is the real party in interest in the present appeal. J. Alexander Marchosky, the inventor, licensed the invention to ISTO Technologies on November 18, 2005.

II. RELATED APPEALS AND INTERFERENCES

Appellants, their assignee and their legal representative are unaware of other appeals or interferences that would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 97, 98, 103-108 are currently pending. Claims 97, 98, 103-108 having been Finally rejected and are now under appeal. The claims on appeal are set forth in full in Appendix 1 to this Brief.

The above captioned application is a divisional application of U.S. Application No. 09/606,768, now United States Patent No. 6,372,257, entitled "Compositions and Methods for Forming and Strengthening Bone" filed June 29, 2000, which claims priority from U.S. provisional application Serial No. 60/141,386 filed on June 29, 1999. This application also claims the benefit of U.S. Application No. 09/377,283 failed March 30, 1999, which claims the benefit of and is a complete application based upon U.S. Provisional application Serial No. 60/135,095, which was converted from a non-provisional application Serial No. 09/050,498 filed March 30, 1998, now abandoned.

This Application was originally filed with 64 Claims. By way of preliminary amendment A on correspondence dated February 7, 2002, claims 5-17, 19-31, 33-49, 51-53, and 61-64 were canceled. New claims 65-76 were added by preliminary amendment B on correspondence dated March 17.

In an Office Action dated October 1, 2004, claims 1, 2, 4, 18, 56, 68, and 69 were rejected under 35 USC §102(e) as allegedly being anticipated by Muschler (US 6,049,026) and claims 1-4, 18, 32, and 50 were rejected under 35 § 103(a) as allegedly being unpatentable over Petrie et al. (US 6,017,940) and Brown et al. (5,629,287). Claims 3, 32, 50, 57-60, 65-67 and 70-75 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Muschler (6,049,026). Claims 54 and 55 were rejected under 35 U.S.C. 101 double patenting (U.S. Patent No. 6,372,257). In a response dated December 16, 2004, Claims 1-55 were cancelled, claims 57 and 72 were amended, claims 76-103 were newly added, claims 56 and 58-60 remained as originally filed, and claims 65-71 and 73-76 were as previously presented. Through Examiner's Amendment following a telephone interview with G. Harley Blosser on May 17, 2005, the following claims were replaced: original claim 56, previously presented claims 68, 69, 71 and 75, previously amended claim 72 and new claims 77, 83, 87, 88, 90, 91, 94-97 and 99-103, with Examiner's claims 56, 68, 69, 71, 72, 75, 77, 83, 87, 88, 90, 91, 94-97 and 99-103.

In an Office action dated June 29, 2005, Claims 56-60 and 65-103 were pending. That Office action stated that Claims 56, 68, and 69 remained rejected under 102(e) as being anticipated by Muschler (US 6,049,026) and Claims 57-60, 65-67 and 70-103 remained rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Muschler (6,049,026). An Advisory Action was mailed on September 14, 2005. In a response dated, October 6, 2005, Claims 1-90 were cancelled, Claims 95, 99, 101 and 102 were amended, and Claims 91-94, 96-98, 100 and 103 remained as previously presented. An RCE was also filed on October 6, 2005. In an interview summary from November 14, 2005, the Office indicated that applicants approved amendments of Claims 95-103 was deemed allowable, however, after reconsideration, claims even as amended were believed (by the Office) to read on EP 0 522 569. An Office action dated November 30, 2005 indicated that Claims 95-103 were now rejected, however, by Examiner's Amendment, Claims 91-94 had also been Canceled. In a response dated March 7, 2006, Claims 1-96 and 99-102 had been canceled, Claims 97 and 103 had been amended, Claim 98 had been twice amended and Claim 104 had been newly added. Following an amendment of Claim 104, a Notice of Allowance was issued on August 24, 2006 for Claims 97, 98, 103 and 104. On June 16, 2006, a Notice of Withdrawal was received from the Office. An Office Action dated August 25, 2006 stated that Claims 97, 98, 103 and 104 were rejected under 35 § U.S.C. 112. In a response dated October 20, 2006, Claims 1-96 and 99-102 stood cancelled, Claims 97, 98, 103 stood as previously presented, Claim 104 was newly amended and Claims 105-108 were newly added. A Final Office action was then mailed on January 17, 2007 in which Claims 97, 98 and 103-108 remained rejected under 35 U.S.C. § 112. In a response sent March 19, 2007, Claims 1-96 and 99-102 had been cancelled, Claims 97, 98, 103, and 105-108 had been previously presented, Claim 104 was newly amended and Claims 109 and 110 were newly added. The Applicants emphasize that in this response, Claim 104 was amended **in accordance with the suggestions of the Examiner in the Office** action dated January 17, 2007, to eliminate the "consisting essentially of" verbiage and the specific composition ratios, suggested as being not in compliance with 35 U.S.C. 112, first paragraph. In fact, the Examiner (see paragraph 2 of that document) had clearly indicated that: **"there is no**

dispute that the specification, at least at paragraphs 9, 11, 24, 46, 48, 51, 60 and 61, supports the general composition of claim 104, as now amended". Claims 109 and 110 were newly added in the same response, presenting the subject matter of original claims 56 and 57. Nevertheless, an Advisory Action mailed April 30, 2007 stated that the newly made amendment to Claim 104 and newly added Claims 109 and 110 would not be entered. A Notice of Appeal was then filed on May 17, 2007. Claims 97, 98, 103-108 are currently pending. **Claims 97, 98, 103-108 having been Finally rejected and are now under appeal.**

Applicants respectfully note that a Notice of Allowance was originally entered in this Application on May 24, 2006, after amendments were made pursuant to an Examiner's interview.

(IV) Status of Amendments

Response to a Final Office action dated January 17, 2007, was mailed on March 19, 2007, at which time, Claims 1-96 and 99-102 had been previously cancelled, Claims 97, 98, 103, and 105-108 had been previously presented, Claim 104 was newly amended and Claims 109 and 110 were newly added. However, the Office states in the Advisory Action dated April 30, 2007, that the amendment made to Claim 104 and the addition of new claims 109 and 110, which were made after Final, would not be entered. According to the Office, Claims 109 and 110 were added without "canceling corresponding number of finally rejected claims. The amendment to claim 104 requires further search and consideration because the open ended comprising language in claim 104 broadens the claims."

(V) Summary of Claimed Subject Matter

Claim 97 Subject Matter.

Applicants refer to paragraphs [0063], [0066], [0068], and [0074] of the specification as originally filed, which has not been modified during prosecution, for support of Claim 97 subject matter. Support for Claim 97 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph. Subject matter of Claim 97 is as follows:

Paragraph [0063] Additionally, other methods to insure the minimal amount of movement of the composition from the site of application may be used. For example, the topical application of calcium to an alginate excipient causes the composition to remain in place, and reduces the flow properties of the composition. The experimental data described below demonstrates the retention properties of a composition using an alginate excipient with the addition of Calcium after the composition has been localized to the site of the bone defect. FIG. 3A illustrates the localized appearance of bone allograft material contained in alginate at one week post-implantation when there was no addition of calcium to the alginate mixture. The allograft was observed to migrate from the defect into the hip joint. In contrast, FIG. 3B shows the localized appearance of bone allograft material contained in alginate at one week post--inplantation where there was an addition of calcium to the alginate mixture immediately after it was placed in the site of bone defect.

Paragraph [0066] This procedure briefly describes the surgical model employed to evaluate the healing potential of bone allograft material in an alginate carrier, following implantation within a clinically significant bone defect. The technique was reproduced from the following reference: Bruder et al., "Bone Regeneration by Implantation of Purified, Culture Expanded Human Mesenchymal Stem Cells," J. Orthopaedic Research 16:155-162 (1998).

Paragraph [0068] Both femurs of athymic nude rats 12-16 weeks of age (National Cancer Institute, Rnu -/-) were exposed via an anterolateral surgical approach as shown in FIGS. 1A and 1B. A predrilled high density polyethylene fixation plate measuring 4 mm.times.4 mm.times.23 mm, with 9 mm pre-drilled center holes (straight) was

subsequently attached to each femur by four (4) Kirschner wires and two (2) cerclage wires as shown in FIG. 1C. A 5 mm transverse segment of the central diaphysis, including the adherent periosteum, was removed using a side cutting burr under saline irrigation as shown in FIG. 2B. Excipients used in the current studies consisted either of 3% alginate from various sources or high viscosity hyaluronic acid (Healon GV, Pharmacia/Upjohn). Bone allograft material was held in place via the apposing musculature, and the fascia and skin were closed using 5-0 Ethibond and 5-0 Ethilon sutures, respectively. Animals were euthanized between 1 and 12 weeks for radiographic evaluation of new bone formation. Femurs were collected and fixed in 10% neutral buffered formalin and processed for histologic evaluation upon staining with either saffranin-O/fast green or geimsa.

Paragraph [0074] Alginate was dissolved in PBS (final concentration 3%) and mixed with bone allograft prior to implantation as described above. Once the defects were filled, calcium chloride solution (50 .mu.l, 5 mM) was applied topically to the alginate/bone material, at which point the excipient material polymerized to form a hardened gel. Identical material in the contralateral limb was left untreated. Animals were sacrificed at 1 and 2 weeks for radiographic evaluation of the implanted bone material, and the tissues were subsequently harvested for histologic evaluation. FIG. 3A illustrates the localized appearance of bone allograft material in alginate without the addition of calcium one (1) week post implantation. The allograft was observed to migrate from the defect into the hip joint where heterotopic ossification occurred within a 12 week period. In contrast, topical application of calcium to the alginate excipient caused the bone allograft to be retained within the defect as shown in FIG. 3B.

Claim 98 Subject Matter.

Applicants refer to Claim 57 and Claims 1-56 which depend from Claim 57, as originally filed, which have been subsequently canceled through prosecution, for support of Claim 98 subject matter. Support for Claim 98 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph. Subject matter of Claim 98 is as follows:

A method of inducing bone formation in a vertebrate comprising applying a composition selected from the group consisting of the compositions of claims 1-56 to a site in the vertebrate where bone formation is desired.

Claim 103 Subject Matter.

Applicants refer to paragraphs [0063], [0066], [0068], and [0074] of the specification as originally filed, which has not been modified during prosecution, for support of Claim 103 subject matter. These paragraphs are as presented above, under **Claim 97** of this section, in this paper. Support for Claim 103 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph.

Claim 104 Subject Matter.

Applicants refer to paragraphs [0009], [0011], [0012], [0060], and [0061] of the specification as originally filed, which has not been modified during prosecution, for support of Claim 104 subject matter. Support for Claim 104 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in these paragraphs. Subject matter of Claim 104 is as follows:

Paragraph [0009] Briefly, therefore, the present invention is directed to a composition comprising the following components: (a) one or more materials selected from the group consisting of fibroblast growth factors, vascular endothelial growth factors, endothelial cell growth factors, transforming growth factors, chitosan, bone, platelet derived endothelial growth factors, placental growth factors, angiogenin, interleukin-8, granulocyte colony-stimulating growth factor, and supernatant fluid from a culture of cells known to produce angiogenic factors; (b) a material comprising demineralized bone matrix, non-decalcified bone matrix, with or without hyaluronic acid; (c) a scaffolding material selected from the group consisting of cancellous bone, chitosan, chitosan-protein, and chitin protein fibers; and (d) a gel material selected from the group consisting of chitosan, imidazolyl chitosan, methylpyrrolidinone chitosan, carbodiimide chitosan, glutaraldehyde chitosan, alginate, a mixture of alginate with chitosan or a chitosan

derivative, hyaluronic acid, and a mixture of hyaluronic acid with chitosan or a chitosan derivative.

Paragraph [0011] Moreover, the present invention is directed to a composition comprising the following components: (a) one or more angiogenesis-stimulating materials selected from the group consisting of fibroblast growth factors, vascular endothelial growth factors, endothelial cell growth factors, transforming growth factors, chitosan, bone, platelet derived endothelial growth factors, placental growth factors, angiogenin, interleukin-8, granulocyte colony-stimulating growth factor, and supernatant from cells known to produce angiogenic factors; (b) an osteoinductive material comprising demineralized bone matrix, non-decalcified bone matrix, with or without hyaluronic acid; (c) a scaffolding material selected from the group consisting of cancellous bone, chitosan, chitosan-protein, and chitin-protein fibers; and (d) a gel material selected from the group consisting of chitosan, imidazolyl chitosan, methylpyrrolidinone chitosan, carbodiimide chitosan, glutaraldehyde chitosan, alginate, and a mixture of alginate with chitosan or a chitosan derivative.

Paragraph [0012] Furthermore, the present invention is directed to a composition for promoting the growth and strengthening of bone comprising a mixture of chitosan or chitosan derivative, cancellous bone, and demineralized bone matrix. The present invention is also directed to a composition for promoting growth and strengthening of bone comprising a mixture of alginate, calcium, cancellous bone, and demineralized bone matrix. Also, the present invention is directed to a composition for promoting growth and strengthening of bone comprising a mixture of chitosan or chitosan derivative, alginate, cancellous bone, and demineralized bone matrix. Additionally, the present invention is directed to a composition for promoting growth and strengthening of bone comprising a mixture of hyaluronic acid, cancellous bone, and demineralized bone matrix.

Paragraph [0060] The composition may be used as a prophylactic treatment to prevent fractures in patients with osteoporosis. In this embodiment, bones which are at risk for fracture in osteoporotic patients are first identified by measuring bone density Bone density is measured using MRI, X-ray, CT-scan, or any other imaging system known in the art for that purpose. The degree of risk for fracture is then assessed based

on the bone density measurement. The bones with the highest risk for fracture are then treated with a composition of the present invention by injecting the composition directly into the bone at the points where risk for fracture is highest. A preferred apparatus for performing these injections is that disclosed in Provisional Patent Application Serial No. 60/132,852 which is herein incorporated by reference. Since the composition must flow through a cannula and into the bone, the composition to be injected must be thinner than compositions which are applied directly to bone defects. An example of a useful composition for this purpose is NBM, 10%; DBM, 10%; cancellous bone, 30%; 2% (w/v) chitosan gel, 50%; 1 mg/ml of a purified vascular endothelial growth factor. Specifically, compositions showing good flow properties may be useful for various applications where the use of a syringe or other similar device is preferred. One example of a useful composition for this purpose is 20% cancellous bone; 20% DBM in 3% alginate. Another example of such a composition with good flow properties is 30% cancellous bone; 10% DBM in 3% alginate. Moreover, another composition with good flow properties is 20.6% (w/w) cancellous bone; 12.4% (w/w) DBM; 0.5% (w/w) alginate; 0.3% (w/w) chitosan; 66.2% (w/w) water. An additional composition showing good flow properties includes 130 mg Hyaluronic acid (HA) solution (1.4% HA solution); 54 mg demineralized bone matrix (DBM);and 130 ng purified vascular endothelial growth factor (VEGF). Another composition with good flow properties is 250 mg of Hyaluronic acid (HA) solution (1.4% sodium hyaluronate); 105 mg demineralized bone matrix (DBM);and 25 ng purified vascular endothelial growth factor (VEGF). Yet another composition with good flow properties is 125 mg Hyaluronic acid (HA) solution (1.4% HA solution); 75 mg of crushed cancellous bone; and 125 ng purified vascular endothelial growth factor (VEGF).

Paragraph [0061] Various formulations of the invention composition may be prepared depending on the particular purpose for its application. An example of a useful composition formulation for this invention is a composition where one or more of the materials is basic fibroblast growth factor, platelet derived endothelial growth factor, or vascular endothelial growth factor present at 10.sup.-6 to 30 mg/ml; the demineralized growth factor is present at 5-30%; the non-decalcified bone matrix is present at 5-30%; the scaffolding material is cancellous bone milled to 0.1-1.5 mm in its longest diameter

and is present at 10-40%; and the gel material is a 0.5%-5% (w/v) concentration selected from the group consisting of chitosan, alginate, hyaluronic acid, a mixture of alginate with chitosan, present at 10-80%, or a mixture of hyaluronic acid and chitosan. For example, when the invention composition is utilized to fill in a large defect, a formulation is utilized which provides a relatively large amount of scaffolding to provide a structure which will support the developing vasculature and bone. An example of such a formulation is: cancellous bone, 40-50%, preferably 40%; DBM, 5-30%, preferably 10%; NBM, 5-30%, preferably 10%; 1 mg/ml of a purified vascular endothelial growth factor; 5% (w/v) chitosan gel, 20-50%, preferably 40%. Another example of a relatively friable composition is 50% (v/v) cancellous bone; 10% (v/v) DBM in 3% alginate.

Claim 105 Subject Matter.

Applicants refer to **paragraph [0061]** of the specification as originally filed, which has not been modified during prosecution, for support of Claim 105 subject matter. This paragraph is as presented above, under **Claim 104** of this section, in this paper. Support for Claim 105 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph.

Claim 106 Subject Matter.

Applicants refer to **paragraph [0061]** of the specification as originally filed, which has not been modified during prosecution, for support of Claim 106 subject matter. This paragraph is as presented above, under **Claim 104** of this section, in this paper. Support for Claim 106 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph.

Claim 107 Subject Matter.

Applicants refer to **paragraph [0061]** of the specification as originally filed, which has not been modified during prosecution, for support of Claim 107 subject matter. This paragraph is as presented above, under **Claim 104** of this section, in this paper. Support

for Claim 107 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph.

Claim 108 Subject Matter.

Applicants refer to **paragraph [0061]** of the specification as originally filed, which has not been modified during prosecution, for support of Claim 108 subject matter. This paragraph is as presented above, under **Claim 104** of this section, in this paper. Support for Claim 108 subject matter is found throughout the specification and therefore is not limited to the particular citations noted in this paragraph.

(VI). Grounds of Rejection to be Reviewed on Appeal

Claims 97, 98 and 103-108 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Newly added Claims 105-108 have been included in the rejection.

(VII). Arguments

Issue 1: Rejection of Claims 97, 98, 103-108 Under 35 U.S.C. § 112

Claims 97, 98, 103-108 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to satisfy the written description requirement. The Office alleges that the Claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant urges that the claims in question fully comply with the written description requirement.

To comply with the written description requirement, "the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." *Fujikawa v. Wattanasin,* 93 F.3d 1559 (Fed. Cir. 1996) at p. 1570. Finding the same wording *(ipsis verbis)* used in the claim is not necessary. *Id.* Thus, so long as a person "of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton,* 76 F3d 1168 (Fed. Cir. 1996) at p. 1175. " . . . [H]ow the specification accomplishes this is not material." *Id.* At p. 1172 (citing *In re Wertheim,* 541 F.2d 257, 262 (C.C.P.A. 1976)."

Notably, **as stated by the Office in the Notice of Allowance**, mailed May 24, 2006, "the claimed composition is a combination of 3 bone types, namely cancellous bone, demineralized bone matrix and non-decalcified bone matrix in the amounts and proportions as claimed. The non-decalcified bone is ground cortical bone, which has not been demineralized and "is known to contain osteoinductive growth factors," according to page 9, lines 14-20 of the specification as originally filed. The as filed specification clearly envisions excluding various parts of the composition as in the composition described on page 6, lines 1-3, and Claim 56, of the specification as originally filed, thus supporting the

consisting essentially of language of claim 104[1]. Claim 104, as presented on Appeal, the principal independent claim, has as its subject matter a composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid/salt thereof, cancellous bone, demineralized bone matrix (DBM), and non-decalcified bone matrix (NBM). Clearly, the instant disclosure demonstrates *applicant had possession of the invention* embodied in claim 104 as one of skill in the art would fairly envision. As indicated in the Examiner's' Communication of May 24, 2006, at ¶ 2), the disclosure directly supports a composition consisting essentially of the three ingredients of a hyaluronic acid/salt, cancellous bone and demineralized bone matrix. (see May 24, 2006 Communication, ¶ 2, citing page 3, line 14 through page 4, line 19, and Claim 56 of the specification as originally filed).

Claim 104 adds to this three-component composition, but one feature - non-decalcified bone matrix (defined on page 9, lines 3-5 and page 16, lines 3-8 of originally filed specification]). Yet the use of the combination of NBM and DBM, as an alternative DBM alone as a constituent of disclosed compositions *for its osteoinductive advantages is expressly provided for* on page 16, lines 5-8, of the specification as originally filed. As stated there: "A combination of non-decalcified bone matrix protein and DBM is also useful in the invention compositions as a source of osteoinductive molecules." (Noting that the acid treatment of DBM leaches out certain osteogenic molecules when DBM is used alone.) Hence, the disclosure clearly demonstrates to one skilled in the art applicant's possession of the invention as embodied in amended claim 104 (with the combination of NBM and DBM noted above as a contemplated alterative to DBM alone *as the osteoinductive component of the composition* appearing at page 16, lines 5-8, and original claim 56. Moreover, as also noted above, the other elements of each of the claims dependent on claim 104, are expressly disclosed in the specification. Accordingly, adequate written description has been demonstrated for claim 104 and the remaining claims. [FN: In the Final Office action, see Office action mailed January 17, 2007, ¶ 3, the Examiner inappropriately urges that since "most" of the disclosure includes growth factors, that a claim "consisting essentially" of the enumerated four ingredients is foreclosed. This is misleading. Provided that "the claimed invention" can fairly be deemed by the skilled artisan to be an embodiment within the applicant's possession - which is demonstrated herein - he is entitled to such a claim. There is no "gist" or

[1] See May 24, 2006 Communication, ¶.2, citing, e.g., to publication ¶.[0012], last three sentences, and to original claim 56.

"majority" of disclosure test required to secure such a claim.]

Therefore, for the reasons presented here, Applicant respectfully urges that the rejection under 35 U.S.C. § 112, first paragraph, was improper and requests that the rejection be overturned on Appeal, with instructions for further proceedings entered so that the application may issue without further delay.

(VIII) Claims appendix

Claims:

1-96. (Previously canceled)

97. (Previously presented) A composition as set forth in claim 104 wherein the bone material consists essentially of bone allograft material.

98. (Previously presented) A method of inducing bone formation in a vertebrate comprising applying a composition as set forth in claim 104 to a site in a vertebrate where bone formation is desired.

99 -102. (Previously canceled)

103. (Previously presented) The method of claim 98 wherein the bone material consists essentially of bone allograft material.

104. (Previously amended) A composition for promoting the growth and strengthening of bone consisting essentially of a mixture of hyaluronic acid or salt thereof, cancellous bone, demineralized bone matrix, and non-decalcified bone matrix [, wherein the hyaluronic acid or salt thereof is present as a 0.5%-5% (w/v) gel concentration at 10-80% (w/w); the cancellous bone is milled to 0.1-1.5 mm in its longest diameter and is present at 10-40% (w/w); the demineralized bone matrix is present at 5-30% (w/w); and the non-decalcified bone matrix is present at 5-30% (w/w)].

105. (Previously added) A composition as set forth in claim 104 wherein the hyaluronic acid or salt thereof is present as a 0.5%-5% (w/v) gel concentration.

106. (Previously added) A composition as set forth in claim 104 wherein the cancellous bone is milled to 0.1-1.5 mm in its longest diameter.

107. (Previously added) A composition as set forth in claim 98 wherein the hyaluronic acid or salt thereof is present as a 0.5%-5% (w/v) gel concentration.

108. (Previously added) A composition as set forth in claim 98 wherein the cancellous bone is milled to 0.1-1.5 mm in its longest diameter.

(IX) Evidence appendix

None.

(X) Related proceedings appendix

None.

(XI) Conclusion

As it is believed Claims 97, 98, 103-108 are in proper form for allowance, Appellants respectfully request the rejections be reversed on this Appeal and Claims 97, 98, 103-108 be allowed. Applicants believe there is no other fee due at this time. However, the Commissioner is hereby authorized to deduct any deficiency or credit any overpayment to Deposit Account No. 19-3140.

Respectfully submitted,

Dated: 8/17/07

By: /G. Harley Blosser/

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